





DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC

JUL 16 2001

Norm Patterson  
Senior Vice President  
Dolco Packaging  
Midwest Division  
2110 Patterson Street  
Post Office Box 469  
Decatur, Indiana 46733-0469

Dear Mr. Patterson:

This responds to a meeting that was held at the Food and Drug Administration (FDA) on April 20, 2001, and a telephone conference call with representatives from Dolco and UEP on June 29, 2001, regarding the placement of the safe handling statement required on the cartons of shell eggs that have not been treated to destroy *Salmonella*. Specifically, you requested that FDA reconsider the position stated in its letter of March 2, 2001, and offer the option of placing the safe handling statement on the inside of the lid ("inlid") of egg cartons.<sup>1</sup>

As you are aware, recently promulgated 21 CFR 101.17(h) requires that the safe handling statement appear on the principal display panel (PDP) or the information panel (65 FR 76092, December 5, 2000, "shell egg labeling rule"). As defined in 21 CFR 101.1 the PDP is the "part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." The information panel is defined in 21 CFR 101.2 as "that part of the label that is immediately contiguous and to the right of the [PDP] ..." or "if the top of the container is the [PDP] and the package has no alternate [PDP], the information panel is any panel adjacent to the [PDP]." Based on these definitions, the inlid of egg cartons does not meet the definition of the PDP or information panel. Thus, placement of the safe handling statement on the inlid does not comply with the placement requirements in 21 CFR 101.17(h)(2).

<sup>1</sup> As you are aware, after publication of the shell egg labeling rule, FDA received letters from Phil Laughlin of Dolco dated January 2 and January 12, 2001, asking that FDA permit the safe handling statement on the inlid of egg cartons. The bases for the request were (1) high costs to change printing plates to print the statement on the outside of egg cartons, (2) lack of space on the PDP due to existing artwork and State and other federal mandatory information, and (3) inability of some lines to print on the side panels (i.e., the information panel). In response to this request, FDA issued a letter dated March 2, 2001, stating that we would permit the safe handling statement on the inlid only when there is insufficient space on the PDP or information panel for all mandatory information. We pointed out that nonmandatory information such as artwork should not be considered when determining sufficiency of label space in accordance with 21 CFR 101.15.

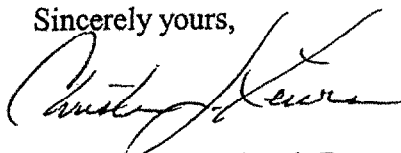
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However, we have considered your requests and we are now reconsidering placement of the statement on the inlid. We plan to issue a proposed rule to amend the regulation in 21 CFR 101.17(h) to include the option of placing the safe handling statement on the inlid. Until this rulemaking is complete, it is unlikely that enforcement of the placement of the safe handling instructions on the inlid will be a high priority as long as the statement on the inlid is prominent. When judging whether the safe handling statement is prominent, we may look to see if there is a referral statement on the PDP that instructs consumers to look at the inlid for the statement. (An example of such a statement is "see safe handling instructions inside.") We may also consider whether any referral statement is in close proximity to the "Keep Refrigerated" statement that is still required by USDA regulations.

We would like to point out that the regulations in 21 CFR 101.17(h)(6) provide that States and localities may under their own jurisdictions enforce 21 CFR 101.17(h). Please understand that States and localities may choose to enforce the regulations as they now stand until they are amended through notice and comment rulemaking.

If you have further questions, please let us know.

Sincerely yours,



Christine J. Lewis, Ph.D.

Director

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